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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,751	06/04/2001	Kenneth M. Phillips	6807.US.01	4856

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EXAMINER	
FISHER, LATONIA M	
ART UNIT	**PAPER NUMBER**
1623	5

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/873,751	Applicant(s) PHILLIPS ET AL.	
	Examiner La Tonia M. Fisher	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-22 are pending.

Claim Objections

Claims 19 and 21 are objected to because of the following informalities: Claim 19 misspells the word "oligosaccharide." Claim 21 seems to be missing some wording in line 3. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waite et al (USPN 5,869,459) in view of John Hopkins Press Release, *Zinc Supplements Important in Combating Diarrhea*, November 27, 2000.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is drawn to a method for providing oral rehydration therapy comprising administering to a human in need thereof, an aqueous solution containing sodium, potassium, zinc, citrate, and a carbohydrate. Claim 2 limits the method of claim 1 wherein said aqueous solution administered in the method also contains chloride. Claim 3 limits the carbohydrate in the aqueous solution used in the method of claim 1 to a mixture of dextrose and fructose. Claims 4-5 delimit claim 1 by specifying the amount of carbohydrate and sodium present in the aqueous solution used in said method. Claim 6 is drawn to the method of claim 1 wherein the sodium is selected from the group consisting of sodium chloride, sodium citrate, sodium bicarbonate, sodium carbonate, sodium hydroxide and mixtures thereof. Claim 7 delimits claim 1 by specifying the amount of potassium present in the aqueous method used in said method. Claim 8 is drawn to the method of claim 1 wherein the potassium is selected from the group consisting of potassium chloride, potassium citrate, potassium bicarbonate, potassium carbonate, potassium hydroxide and mixtures thereof. Claims 9-10 delimit claim 1 by specifying the amount of zinc present in the aqueous method used in said method. Claim 11 is drawn to a method according to claim 1 wherein the zinc is selected from the group consisting of zinc gluconate, zinc sulfonate,

zinc chloride, zinc acetate, zinc sulfate, zinc fluoride and zinc bromide. Claim 12 delimits claim 1 by specifying the amount of chloride present in the aqueous method used in said method.

Claim 13 is drawn to a method according to claim 1 wherein the chloride is selected from the group consisting of potassium chloride, sodium chloride, and zinc chloride. Claim 14 delimits claim 1 by specifying the amount of citrate present in the aqueous method used in said method. Claim 15 is drawn to a method according to claim 1 wherein the citrate is selected from the group consisting of potassium citrate, sodium citrate, and citric acid.

Waite et al. discloses a method for providing electrolytes to a child in need thereof comprising providing a rehydryating composition comprising, sodium, potassium, chloride, water, and a carbohydrate selected from the group consisting of xylose, ribulose, dextrose, glucose, mannose, galactose, fructose, sucrose, maltose, and mixtures thereof. See USPN '459, claim 4. In addition, Waite et al. teaches that the suspending agent included in the oral rehydrating solution administered may be xanthan gum, gum karaya, gum tragacanth, or gum acacia. USPN '459, col. 7, lines 33-39. Claims 1-4 also disclose the oral rehydration solution can be frozen and may come in sealed freezable packaging materials.

Waite et al. does not disclose an oral rehydration solution explicitly containing zinc. However, Waite et al. teaches that the rehydrating composition may also contain zinc chloride at column 7, line 11.

It is disclosed in a press release released by John Hopkins School of Public Health that when zinc was given in conjunction with oral rehydration therapy during recovery from acute or persistent diarrheas, zinc supplements helped children suffering from acute and persistent diarrhea significantly reduce the duration of their symptoms.

The active agents and designated concentrations set forth in the prior art overlap substantially with the active agents and concentrations instantly claimed. See USPN '459, col. 5, lines 20-36 for further emphasis. Thus, it would have been obvious for one having ordinary skill in the art at the time the invention was made to combine sodium, potassium, zinc, citrate, water, chloride and carbohydrate(s) to form an oral rehydration solution and administer the solution to a human in need thereof as the applicant's have done with the references before them. It requires no more than routine skill in the art to combine art recognized active agents to form an oral rehydration solution and administer the combined composition to treat dehydration and related symptoms and conditions since the art discloses the theses agents are shown to treat dehydration either individually or when used in combination. Applicants would have been particularly motivated to include zinc in the present invention as Waite et al. suggests the use of zinc chloride in the invention and the John Hopkins press release evidences zinc is recognized in the art for its therapeutic effect in treating dehydration and related symptoms and conditions.

Claims 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waite et al (USPN 5,869,459) in view of John Hopkins Press Release, *Zinc Supplements Important in Combating Diarrhea*, November 27, 2000 and Ndife et al. (USPN 5,489,440).

Claim 16 is drawn to an oral rehydration solution comprising sodium, potassium, zinc, citrate, water and a carbohydrate. Claim 17 limits the oral rehydration solution of claim 16 wherein the solution further comprises a gelling agent. Claim 18 is drawn to an oral rehydration solution as claimed in claim 16 further comprising rise flour. Claim 19 limits the oral rehydration solution of claim 16 wherein the solution further comprises an indigestible oligosaccharide.

Claims 20-22 are drawn to articles of manufacture comprising the oral rehydration solution of claim 16 packaged in a unit dose container which may or may not contain instructions and labels concerning freezing the oral rehydration solution prior to consumption.

Each of Waite et al. and John Hopkins Press Release, *Zinc Supplements Important in Combating Diarrhea*, November 27, 2000 teaches as set forth above.

Neither Waite et al. nor John Hopkins Press Release, *Zinc Supplements Important in Combating Diarrhea*, November 27, 2000 teaches an oral rehydration solution comprising rice flour.

Ndife et al. discloses compositions for oral rehydration comprising electrolytes and rice flour and methods of administering same. See USPN '440, claims 1-14. Ndife et al. teaches that the electrolytes useful in the invention are potassium chloride, sodium citrate, citric acid and sodium chloride. USPN '440, col.4, lines 34-37.

As for the written instructions in claims 21-22 of the present invention, it should be noted that instructions and packaging do not hold patentable weight. It is the nature of kits to come with labels and instructions. Unless the writing has a "functional relationship" with the article of manufacture, it is not a patentable limitation.

The active agents and designated concentrations set forth in the prior art overlap substantially with the active agents and concentrations instantly claimed. See USPN '459, col. 5, lines 20-36 for further emphasis. Thus, it would have been obvious for one having skill in the art at the time the invention was made to combine sodium, potassium, zinc, citrate, water, a carbohydrate and rice flour to form an oral rehydration solution as the applicant's have done with the references before them. It requires little more than routine skill in the art to combine art

recognized active agents to form an oral rehydration solution and administer the combined composition to treat dehydration and related symptoms and conditions since the art discloses the theses agents are shown to treat dehydration either individually or when used in combination. Applicants would have been particularly motivated to include zinc in the present invention as Waite et al. suggests the use of zinc chloride in the invention and the John Hopkins press release evidences zinc is recognized in the art for its therapeutic effect in treating dehydration and related symptoms and conditions. Likewise, Applicants would have been equally motivated to include rice flour in the present invention as Ndife et al. teaches that oral rehydration solutions containing rice flour are beneficial because oral rehydration solutions that contain rice flour not only replace fluid and electrolytes, but also decrease stool volume, reduce duration of diarrhea and may have some nutritive value. See USPN '440, col. 7, lines 48-53 for further emphasis.

Conclusion

Claims 1-22 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to La Tonia M. Fisher whose telephone number is (703) 306-5819. The examiner can normally be reached on Monday - Friday from 9:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

KATHLEEN K. FONDA
PRIMARY EXAMINER